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09/734,755	12/12/2000	Robert B. Schock	DATA_53	4827

7590

07/30/2002

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EXAMINER

PATEL, NIHIR B

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/734,755

Applicant(s)

SCHOCK ET AL.

Examiner

Nihir Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 14, and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-13 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the second species or the embodiment of figure 3 drawn to claims 1 through 19 is acknowledged.
2. Claims 2,3, and 4 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim.

Drawings

3. Figure 1 is objected to because it fails to show numeral 21 (tip lumen). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 5 through 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Referring to claim 1, there is insufficient antecedent basis for limitations "the outer tube", "the balloon membrane", "the tip", "the inner tube", and "the fiberoptic sensor".

Referring to claim 5, there is insufficient antecedent basis for limitations "the inner tube" and "the fiberoptic fiber".

Referring to claim 6, there is insufficient antecedent basis for limitations “the inner tube”, “the outer tube”, “the fiberoptic fiber”, “the balloon membrane”, “the balloon portion”, and “the outer lumen”.

Referring to claims 7 and 17, there is insufficient antecedent basis for limitations “the inner tube” and “the outer tube”.

Referring to claim 8, there is insufficient antecedent basis for limitations “the tip”, “the fiberoptic sensor”, and “the pressure sensing surface”.

Referring to claim 9, there is insufficient antecedent basis for limitations “the pocket”, “the outer surface”, “the tip”, and “the inner surface”.

Referring to claim 10, there is insufficient antecedent basis for limitations “the outer surface”, “the tip”, and “the pocket”.

Referring to claim 11, there is insufficient antecedent basis for limitations “the pocket”, “the inner surface”, “the tip”, and “the outer surface”.

Referring to claims 12,13,14,15, and 19, there is insufficient antecedent basis for limitations “the pocket”.

Referring to claim 16, there is insufficient antecedent basis for limitations “the outer tube”, “the balloon membrane”, and “the tip”.

Referring to claim 18, there is insufficient antecedent basis for limitations “the inner lumen extension tube”, “the balloon membrane”, “the co-lumen tube”, “the tip”, and “the fiberoptic sensor”.

Claim Objections

5. Claims 14 and 15 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 12. See MPEP § 608.01(n). Accordingly, the claims 14 and 15 not been further treated on the merits.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Valley et al. U.S.

Patent No. 5,795,325. Referring to claim 1, Valley discloses methods and apparatus for anchoring an occluding member that comprises a balloon membrane (310), a tip (332), a fiberoptic sensor (330) connected to the tip (332), a fiberoptic fiber (334 and 336), an outer tube (304), and an inner tube (302) disposed within an outer surface of the outer tube (304), the inner tube extending beyond a distal end of the outer tube, a distal end of the balloon membrane (310) being connected to the tip (332) and to a distal end of the inner tube (302), the fiberoptic fiber (334 or 336) being connected on a distal end to the fiberoptic sensor (330) and proximal to the fiberoptic sensor (330) being at least partially connected along its length to the inner surface. Refer to figures 7A, 7B, and 7C and column 17 lines 5 through 40.

Referring to claim 6, Valley shows that the inner tube (302) is connected to the outer tube (304), an inner surface of the outer tube (304) defines an outer lumen, and the fiberoptic fiber has a balloon portion (316) which is disposed with the balloon membrane and an outer tube portion

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which is disposed within the outer tube (304), the balloon portion of the fiberoptic fiber (334 or 336) is connected to the inner tube, the outer tube portion of the fiberoptic fiber is disposed within the outer lumen. Refer to figures 7A, 7B, and 7C and column 17 lines 5 through 40.

Referring to claim 7, Valley shows that the inner tube (302) is connected to the outer tube (304) and comprises two tubes connected end-to-end. Refer to figure 7A.

Referring to claim 16, Valley discloses methods and apparatus for anchoring an occluding member that comprises a fiberoptic sensor (330) catheter and a balloon catheter, the balloon catheter comprising a balloon membrane (310), a tip (332) having a tip lumen, an outer tube (304), and an inner tube (302) disposed within an outer surface of the outer tube (304), the inner tube (302) extending beyond a distal end of the outer tube (304), a distal end of the balloon membrane (310) being connected to the tip and to a distal end of the inner tube (302), the fiberoptic sensor catheter comprising a tube having a fiberoptic sensor (330) connected to a distal end of a fiberoptic fiber (334 or 336) which is connected to the tube, the fiberoptic sensor catheter fitting within the inner tube (302) and in the tip lumen. Refer to figures 7A, 7B, and 7C and column 17 lines 5 through 40.

Referring to claim 17, Valley shows that the inner tube (302) is connected to the outer tube. Refer to figure 7A.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Valley et al. U.S. Patent No. 5,795,325 in view of Kolff U.S. Patent No. 5,370,640.

Valley discloses the applicant's invention as claimed with the exception of stating that the fiberoptic fiber is adhered to an outer surface of the inner tube.

Kolff discloses an intracorporeal catheter placement apparatus and method that does state that the fiberoptic fiber can be adhered to an outer surface of the inner tube. There for it would be obvious to modify Valley's invention by stating that the fiberoptic fiber is adhered to an outer surface of the inner tube so that the pressure sensor can give an accurate reading.

Claims 8,9,10,11,12,13,18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valley et al. U.S. Patent No. 5,795,325 in view of Weldon et al. U.S. Patent No. 5,419,765.

Referring to claim 8, Valley discloses the applicant's invention as claimed with the exception of providing a balloon catheter that comprises a pocket.

Weldon discloses a wound treating device and method for treating wounds that does provide a balloon catheter that provides a pocket. Therefore it would be obvious to modify Valley's invention by providing a balloon catheter that comprises a pocket so that one knows the limitations of the invention.

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Referring to claim 9, Valley discloses the applicant's invention as claimed with the exception of providing a balloon catheter that comprises a pocket that extends from the outer surface of the tip to a point between the inner surface of the tip and the outer surface of the tip.

Weldon discloses a wound treating device and method for treating wounds that does provide a balloon catheter that provides a pocket that extends from the outer surface of the tip to a point between the inner surface of the tip and the outer surface of the tip. Therefore it would be obvious to modify Valley's invention by providing a balloon catheter that comprises a pocket that extends from the outer surface of the tip to a point between the inner surface of the tip and the outer surface of the tip in order to deliver the treating agent quickly.

Referring to claim 10, Valley discloses the applicant's invention as claimed with the exception of providing a tip in which the outer surface comprises a distal sloping portion and wherein the pocket extends from the distal sloping portion to a point between the distal sloping portion and the proximal end of the tip.

Weldon discloses a wound treating device and method for treating wounds that does provide a balloon catheter that provides a tip in which the outer surface comprises a distal sloping portion and wherein the pocket extends from the distal sloping portion to a point between the distal sloping portion and the proximal end of the tip. Therefore it would be obvious to modify Valley's invention by providing a tip in which the outer surface comprises a distal sloping portion and wherein the pocket extends from the distal sloping portion to a point between the distal sloping portion and the proximal end of the tip in order to deliver the treating agent quickly.

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Referring to claim 11, Valley discloses the applicant's invention as claimed with the exception of providing a balloon catheter that comprises a pocket that extends from a point between the inner surface of the tip and the outer surface of the tip to the inner surface of the tip such that it communicates with the inner lumen.

Weldon discloses a wound treating device and method for treating wounds that does provide a balloon catheter that comprises a pocket that extends from a point between the inner surface of the tip and the outer surface of the tip to the inner surface of the tip such that it communicates with the inner lumen. Therefore it would be obvious to modify Valley's invention by providing a balloon catheter that comprises a pocket that extends from a point between the inner surface of the tip and the outer surface of the tip to the inner surface of the tip such that it communicates with the inner lumen in order to provide enough space to store the treating agent.

Referring to claim 12, Valley discloses the applicant's invention as claimed with the exception of providing a balloon catheter that comprises a pocket that is filled with a protective material.

Weldon discloses a wound treating device and method for treating wounds that does provide a balloon catheter that comprises a pocket that does provide a balloon catheter that states that the pocket can be filled with any desired material. Therefore it would be obvious to modify Valley's invention by providing a balloon catheter that states that the pocket can be filled with protective material or any desired material so that one knows the limitations of the invention.

Referring to claim 13, Valley discloses the applicant's invention as claimed with the exception of providing a balloon catheter that comprises a pocket that is filled with a gel.

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Weldon discloses a wound treating device and method for treating wounds that does provide a balloon catheter that comprises a pocket that does provide a balloon catheter that states that the pocket can be filled with any desired material such as gel. Therefore it would be obvious to modify Valley's invention by providing a balloon catheter that states that the pocket can be filled with gel or any desired material so that one knows the limitations of the invention.

Referring to claim 18, Valley discloses the applicant's invention as claimed with the exception of providing a balloon catheter that comprises of a pocket.

Weldon discloses a wound treating device and method for treating wounds that does provide a balloon catheter that comprises of a pocket. Therefore it would be obvious to modify Valley's invention by providing a balloon catheter that does comprise of a pocket so that one knows the limitations of the invention.

Referring to claim 19, Valley discloses the applicant's invention as claimed with the exception of providing a pocket that is filled with a protective material and wherein the pocket is sealed by a membrane.

Weldon discloses a wound treating device and method for treating wounds that does provide a balloon catheter that comprises of a pocket that can be filled with any desired material such as protective material and is sealed by a membrane. Therefore it would be obvious to modify Valley's invention by providing a balloon catheter that comprises of a pocket that can be filled with any desired material such as a protective material and is sealed by a membrane so that one knows the limitations of the invention and that the treating agent can be sealed in a tight environment.

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Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Nihir Patel whose telephone number is (703) 306-3463. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful the examiner supervisor Henry Bennett can be reached at (703) 308-0101.

NP
July 16, 2002

Henry Bennett
Supervisory Patent Examiner
Group 3700